

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 18 APR 2005

PCT WIPO PCT

To:
RICHARD C. PEET
FOLEY & LARDNER LLP
WASHINGTON HARBOUR
3000 K STREET, N.W. SUITE 500
WASHINGTON, DC 20007-5143

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 058951-0183		Date of mailing (day/month/year) 15 APR 2005
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US04/17424	International filing date (day/month/year) 25 June 2004 (25.06.2004)	Priority date (day/month/year) 27 June 2003 (27.06.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): C12N 15/10,15/29,15/82,15/84; A01H 1/00 and US Cl.: 435/91.2; 536/23.6; 800/260,278,294		
Applicant J.R. SIMPLOT COMPANY		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer David T. Fox Telephone No. 571 272-1600
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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☒ in written format
☒ in computer readable form
 - c. time of filing/furnishing
☒ contained in international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:
- See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-3 and 41-43

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-2 and 42</u>	YES
	Claims <u>3, 41 and 43</u>	NO
Inventive step (IS)	Claims <u>1-2</u>	YES
	Claims <u>3 and 41-43</u>	NO
Industrial applicability (IA)	Claims <u>1-3 and 41-43</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-2 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of using PCR to identify T-DNA-like plant sequences, particularly using the primers claimed in claim 2.

Claim 42 meets the criteria set out in PCT Article 33(2), because the prior art does not teach a nucleic acid molecule with 100% identity to SEQ ID NO: 97.

Claims 1-3 and 41-43 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claim 3 lacks novelty under PCT Article 33(2) as being anticipated by YODER et al (US 5,482,852 A).

YODER et al teach the claimed method of plant transformation with a vector comprising T-DNA and P-DNA in the form of plant-derived transposons capable of inserting exogenous DNA into the plant genome, wherein the P-DNA is subsequently lost following crossing and obtaining progeny (see, e.g., Figures 1-3; column 2, line 57 through column 3, line 28; column 14, line 50 through column 21, line 20).

Claim 41 lacks novelty under PCT Article 33(2) as being anticipated by COOKE et al (US 6,103,893 A).

COOKE et al teach a nucleic acid molecule with 92.5% sequence identity to SEQ ID NO: 96 (see, e.g., Sequence Listing of columns 11-16, and appended sequence search result).

Claim 43 lacks novelty under PCT Article 33(2) as being anticipated by NATIONAL STARCH (WO 96/34968 A2).

NATIONAL STARCH teaches a nucleic acid molecule with 95.0% local similarity and 85.8% overall similarity to SEQ ID NO: 97 (see, e.g., pages 53-55, SEQ ID NO: 18, and appended sequence search result). The nucleic acid molecule of NATIONAL STARCH would inherently possess at least 90% overall similarity to SEQ ID NO: 97 if the gap parameters and other parameters were adjusted differently.

Claims 42-43 lack an inventive step under PCT Article 33(3) as being obvious over NATIONAL STARCH (WO 96/34968 A2).

NATIONAL STARCH teaches a nucleic acid molecule identical to SEQ ID NO: 97 except for 12 base pair internal gap, which is a starch branching enzyme gene (see, e.g., page 21, bottom paragraph; pages 53-55, SEQ ID NO: 18, and appended sequence search result). The gap appears to have been a sequencing error, an artefact of DNA isolation, or a mutation. It would have been obvious to re-isolate DNA from the potato plant taught by NATIONAL STARCH for the obtention of other useful starch synthesis genes, including that of SEQ ID NO: 97.